UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/342,314 | 06/29/1999 | MICHAEL J. YELLIN | C014CIP/DIV2 | 6376 |

7590 01/13/2003

JAMES F. HALEY, JR. ESQ. FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020

| EXAMINER |
|---|
| GAMBEL, PHILLIP |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 09/342,314 | YELLIN |
| | Examiner | Art Unit |
| | GAMBEL | 1644 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☑ Responsive to communication(s) filed on 9/26/01

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☑ Claim(s) _____ is/are pending in the application. 1, 103-108, 112-127, 130-131

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1, 103-108, 112-127, 130, 131

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

1. The request filed 9/26/02 (Paper No. 21) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/343,314 is acceptable and a CPA has been established.
An Office Action on the CPA follows

Claims 1, 103-108, 112-127 and 130-131 are pending and being acted upon presently.

Claims 2-102, 109-111, 128 and 129 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
The rejections of record can be found in the previous Office Action (Paper Nos. 11/14).
Given the absence of additional rebuttal to the outstanding rejections of record in applicant's amendment, filed 9/26/02 (Paper No. 21); the rejections are maintained for the reasons of record.

3. Claims 1 and 103-105, 109, 112-117 and 130-131 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Wilson et al. (U.S. Patent No. 5,652,224) essentially for the same reasons of record set forth in Paper Nos. 11/14.

Claims 1, 103-108, 112-127 and 130-131 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wilson et al. (U.S. Patent No. 5,652,224) in view of art known methods of generating modified antibodies of interest, as acknowledged by applicant on pages 13-15 of the instant specification and in view of Lederman et al. (WO 93/09812; 1449), essentially for the same reasons of record set forth in Paper Nos. 111/4.

Applicant's arguments, filed 8/6/01 (Paper No. 13), were fully considered but are not found convincing essentially for the reasons of record set forth in Paper Nos. 11/14.

Applicant acknowledged that Wilson et al. teach the use of gene therapy vectors in combination with immunomodulators such as anti-CD40L antibodies to treat various disorders including atherosclerosis.

Applicant asserted that the teachings of Wilson et al. are directed to the co-administration of immune modulators such as CD40L-specific antibodies in order to inhibit immune responses, which is clearly limited to the prevention of immune responses which develop as a result of delivery of the gene therapy vector.

In contrast to the teachings of Wilson et al.; applicant argued that the instant claims are directed to the treatment of atherosclerosis with an antibody that inhibits the interactions between the CD40L and CD40, thereby preventing the activation of CD40-bearing cells, which play a role in atherosclerosis.

Applicant asserted that the instant methods are effective irrespective of whether the patient suffers from an underlying metabolic disorder.

Applicant argued that Wilson et al. does not teach methods of treating atherosclerosis by administering CD40L-specific antibodies in order to inhibit the interaction between CD40L and CD40, thereby preventing the activation of CD40-bearing cells.

In addition, applicant argued that neither White et al. nor Lederman et al. teach specific dosages that inhibit the interaction between CD40L and CD40 bearing cells recited in the instant claims.

In response to applicant's argument's in conjunction with In re Ochiai that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). See MPEP 2145.

Also, it was noted that obviousness can be established for achieving the claimed product for different reasons and the prior art / examiner does not need to know all of the properties of the claimed invention In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990); however there must be some suggestion or motivation. Therefore, the reason or motivation to combine may often suggest doing what the inventor has done, but for a different purpose or to solve a different problem than that asserted by the inventor. See MPEP 2144.

As pointed out previously, it was noted that the claimed methods recite "comprising" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03.

With respect to inherency as well as obviousness; it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure, given the open "comprising" language.

As acknowledged by applicant; Wilson et al. does teach the use of gene therapy vectors in combination with immunomodulators such as anti-CD40L antibodies (column 17, paragraph 4) to treat various disorders including atherosclerosis (see entire document, including Background of the Invention, and Detailed Description of the Invention).

In contrast to applicant's recitation of comprising; applicant was invited to consider amending the claims to recite "consisting essentially of" and distinguishing the claims from the prior art according to the following. See MPEP 2111.03.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not *materially* affect the *basic* and *novel* characteristic(s)" of the claimed invention. *In re Herz* , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co.* v. *E.I. duPont de Nemours & Co.* , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp.* v. *Calco, Ltd* ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.").

Also with respect to inherency; see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); and Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) and Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Given the teachings that the immunomodulator anti-CD40L antibodies would be beneficial in the treatment of atherosclerosis and the teachings that 5C8-/CD40L-specific antibodies affect a number of cell interactions; the claimed effects on transmigration, blood vessels, endothelial cells and smooth muscle cells would have been expected given the ability to inhibit CD40L-mediated responses including the inhibition of atherosclerosis.

Also, as pointed out previously, the claimed dosages and routes of administration were known and practiced at the time the invention was made and/or would have been encompassed in providing for sufficient therapeutic intervention depending on the patient's needs at the time the invention was made.

One of ordinary skill in the art at the time the invention was made would have been motivated to select the ability of CD40L-specific antibodies in combination with a gene therapy to inhibit atherosclerosis. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been found persuasive.

4. No claim is allowed.

5. All claims are drawn to the same invention claimed in the parent application prior to the filing of this continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
January 13, 2003